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Panel discussion

Guidelines and performance: Creating a culture of ethics

WHAT CHANGES INSTITUTIONAL CULTURE?

Ms. Ehringhaus: I'd like to lead off this discussion with a couple of very fundamental questions: How do we define ethics, and what are the markers of a culture of ethics? Dr. Soule, since you've written a good bit in this area, I'll let you tackle this one.

Dr. Soule: I think I would say that ethics involves an informal system of behavioral norms whose purpose is to reduce harm to others. In the medical context, the key areas where ethics matter would seem to center around the patient's interaction with the doctor and the hospital. So a positive ethical culture would be one in which people put patient welfare ahead of everything else—not because "it says so" in the code of conduct, but intuitively. When novel situations arise or when the best course isn't completely clear, that interaction with the patient will be the default priority if the organization has a positive ethical culture.

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Ms. Ehringhaus: Can you give us an example of an organization that turned itself around by creating a culture of ethics?

Dr. Soule: As Dr. Miller said in his presentation, changing culture is very difficult, but it does happen. It tends to work most effectively after a scandal: new people are usually brought in, everyone is held accountable, and creating a culture of ethics becomes a high priority. My biggest worry in such situations is that the gains will be followed by backsliding: culture can be incredibly unstable. The only way to prevent backsliding is through systematic assessment and making the assessments transparent. I don't subscribe to the theory that "we manage what we measure"; we measure all kinds of things that never get managed. On the other hand, if something is not measured, it is not likely to be attended to.

Ms. Ehringhaus: Dr. Miller, what's your take on this from the academic medical center perspective? Just how capable are medical institutions of either turning themselves around or enhancing their existing culture? Does your experience at Johns Hopkins speak to this?

Dr. Miller: I think the death of Ellen Roche [a previously healthy 24-year-old who died from volunteering in a 2001 medical research study at Johns Hopkins University] had a dramatic effect on the whole issue of human subject protection at Hopkins. In some ways, we as researchers were somewhat arrogant, believing that we knew the best ways to do things, and then this happened. Since then, incredible safeguards have been put in place, and employees have been trained to know the rules. When employees comply with those rules, the work of the institutional review board is more effective. I think we have a very good program, but it took this event to bring Hopkins to its knees, and we all felt it. Another important event was the death of Josie King [an 18-month-old child who died due to medical error at Johns Hopkins Hospital in 2001]. Such events can galvanize an institution to really change.

Ms. Ehringhaus: Does it take a sentinel event to prompt real change?

Dr. Soule: It doesn't hurt. New leadership can also bring about change in an institution's culture. One example is when Paul O'Neill, who since served as US treasury secretary, became CEO of Alcoa. When he arrived, Alcoa already had a good worker safety

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record, but he made worker safety a key priority and drove the accident rate down to virtually zero. How he did it is a great case study in how to alter a culture. First of all, he made safety his personal priority. Second, he terminated a highly ranked superstar—an employee manager in Brazil—for failing to report an injury within 24 hours of its occurrence. Interestingly, since O'Neill left Alcoa, safety measures have continued to improve—an indication that a real cultural shift occurred.

Dr. Miller: I understand that O'Neill also had his computer set up so that every morning the first thing he saw on his monitor was a report of injuries and accidents at Alcoa worldwide so that he could identify trends early.

BUSINESS AND ACADEME: IS THE ANALOGY VALID?

Question from audience: Are businesses really a good model for academe? Businesses come and go, make mistakes, fail, and declare bankruptcy. They are sometimes dissolved, and their leaders are sent to jail. Academic institutions, with few exceptions, seem to never go away. We've had some of the same academic institutions for the past 300 years even though some have had their share of missteps along the way. Are they just better than businesses? Or is there a kind of institutional resilience in academe that's just different in character?

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Dr. Miller: Academic institutions have a resilience that no other institutions have. Those of us in leadership positions at an academic institution know that we hold our positions for only a short time. We try to protect the institution and make it move forward. We're going to make mistakes, but a place like Johns Hopkins that has so much tradition can withstand much because of its culture and heritage. I don't think the situation is comparable in many companies.

Dr. Soule: Although there are big differences between the two models, they also have a tremendous amount of overlap. I think that both, frankly, can learn from one another. One of the big differences between the two models is that education has been a growth industry for the last 300 years, and that doesn't happen with many products or services.

Another difference, and an interesting one, is that bribery has found its way into virtually every nook and cranny of corporate America, but if you look at a university, about the only place you might expect to find bribery is on the admissions committee, since admission is probably the most precious resource the university has, which relates to education being a perennial growth industry. Of course, money is not the only corrupting force: status and prestige are very important in academe, but they generally are not qualities that are enhanced by rigging the system.

MEDIA INFLUENCE ON INSTITUTIONAL CULTURE

Question from audience: I'd like to revisit the Johns Hopkins case with the cosmetics company that Dr. Miller mentioned in his talk. He said that Johns Hopkins' relationship with the company "didn't fly" with the public, but how do we know that it merely didn't fly with a few reporters from a couple of newspapers? To what extent do the media accurately reflect the culture in medicine, and to what extent does media attention guide what we do as institutions?

Dr. Miller: That's a good point, because about 5 weeks after the *Wall Street Journal* broke the story, the *New York Times Magazine* ran an article that was actually quite positive. It said that this was an area where research was needed and that Hopkins conducted itself very well: we disclosed all interests and did not perform the actual research. So, two totally different sides were taken by two newspapers: the *Wall Street Journal* looked at the darker side of the picture, while the *New York Times* was very positive. How things are presented can be very important to public opinion.

Question from audience: I was interested in the comments in your presentation, Dr. Miller, about creating a culture of ethics not just at Johns Hopkins but on a broader stage. You mentioned efforts to educate the public—can you expand on that? The public's ability to weigh and evaluate differing media accounts such as the ones you just mentioned depends on how well we educate the public about how we do things, especially if we are proud of our activities.

Dr. Miller: I don't have all the answers on this, but after the death of Ellen Roche, Johns Hopkins invited the *Baltimore Sun* newspaper to do a retrospective piece on what occurred and the changes we have made since. There's also an upcoming public television story that will deal with the Josie King death, and it too will highlight changes that have been implemented at Hopkins and at other institutions to improve the culture of safety. We've tried to use the media when we can, as well as to

take other opportunities to get our programs in front of the public, such as by meeting with top government agency officials, testifying before Congress, and the like.

DOES MANDATORY ETHICS TRAINING WORK?

Question from audience: Our academic institution is planning to implement mandatory ethics training for all employees, with separate modules for investigators and institutional officials. Are such programs effective in developing a culture of compliance?

Dr. Miller: As we were developing our policy at Johns Hopkins, the comment we heard over and over again from employees was, "First tell us the rules." People wanted to know the parameters and what they should be thinking about. We've found that employees are now more apt to disclose than before: if they believe they are even close to the threshold for disclosure, now they would rather disclose than not. I don't know whether that really fixes the culture, but at least we're past the time when not everyone knew what the rules were.

Dr. Soule: It's hard to generalize about this question. The answer depends on the training and the circumstances under which it is delivered. For example, after WorldCom entered bankruptcy, every person in the company had to go through ethics training, which was just a prescription for cynicism. Employees felt, "We didn't do anything wrong, yet here we are sitting in this training." On the other hand, if the senior people are really a part of the process, the organization is telegraphing the message that this really matters.

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LEADERSHIP, COMPLIANCE, AND CULTURE

Question from audience: I'm a little perplexed by some apparent contradictions in your advice, Dr. Soule. You stress the importance of leadership, but on the other hand you say that leadership is overrated as a key component. Also, while you say that compliance systems are essentially fragile and that efforts to improve compliance yield diminishing returns, you emphasize that enhancing a culture of compliance is central to creating an ethical culture.

Dr. Soule: I'm afraid I didn't have enough time to do the subject justice. The basics of what I was trying to recommend are assessment, responsibility, and accountability. Assessment is critical because you can't really manage something unless you have good assessment to determine what is actually occurring at the institution. Next, someone must be held responsible in each operational area—such as a business unit or a clinic—for either maintaining a healthy culture or improving a culture that is inadequate. When assigning that responsibility, the institution must provide resources to assist managers in moving in the right direction. Then these managers must be held accountable. This is directly analogous to quality improvement, which can also pose difficult, idiosyncratic, and intangible management issues. In short, reduce the job to accountable responsibilities and make it part of a manager's job description and rewards.

Question from audience: I'd like to go back to the question of whether training and education are effective in changing a culture. As an administrator of an academic health center, I look to the example of when we were fined enormous sums of money after the Physicians at Teaching Hospitals (PATH) audits because of compliance problems with billing and coding systems. Across the country health institutions implemented comprehensive training programs to teach physicians how to properly code and bill to be compliant. Did that change the culture? I don't know, but it certainly changed what our academic physicians do, and for the most part it has made a big difference. These programs must be offered on an ongoing basis because new people arrive and new rules are developed.

Dr. Miller: Having lived through the PATH audits with everyone else, I think it improved things at our institution. Other areas where we have spent a lot of time on compliance have also undergone positive changes, such as billing operations, animal care, and human subject protection. I think that embedding compliance into everyday activities is preferable to making it an add-on activity: everywhere that we've been able to build compliance into our activities we have improved our operations.

Dr. Soule: We need to calibrate our expectations. The goal is not perfection, and it can't be as long as human beings are involved. No one can take responsibility for the ethical conduct of another person, but we can and should take responsibility for the environment in which people work, because that can be controlled. I have noticed that when an ethical fail-

ure occurs, organizations with a strong ethical bearing actually get stronger. For others, such a failure simply reinforces what is already wrong with them.

WHAT DOES DISCLOSURE REALLY ACCOMPLISH?

Question from audience: Can you expand on the issue of disclosures? Dr. Soule mentioned that disclosures aren't a full antidote. I know that sometimes they can become a "solution" that simply maintains the status quo. Some studies have shown that disclosures can actually have the opposite effect of what they should accomplish: they may allow institutions to "strategically exaggerate" to make it seem that they are towing the ethical line. It would be interesting to apply social psychology research to evaluate how conflict-of-interest disclosure affects people's interpretation of medical research. We all want evidence-based information regarding conflicts of interest, but I think our discussions here suffer from a lack of such evidence.

Dr. Soule: Don't misunderstand me that we shouldn't put too much on disclosures: there is no excuse for not disclosing risk to the people you have a duty to, especially if they trust you. Studies show that the trust the public has for physicians is off-the-charts high, and the percentage of those who answer that they "don't trust physicians" is statistically insignificant. In such a situation, the duty to disclose is paramount.

As you said, however, we shouldn't think that this is all that is needed. For instance, the disclosure required by the Sarbanes-Oxley Act for conflict of interest between research analysts and investment banks involves multiple pages of tiny print that no one will read. As a result, I believe it has no impact whatsoever.

Dr. Miller: One positive but intangible aspect of disclosure is that faculty members are forced to regularly think, "Do I have something to disclose?" Being forced to disclose keeps the issue in front of everybody and helps to build an ethical culture.